DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group (I), claim(s) 1, 2(part), 3, and 8(part), drawn to compounds wherein the core is a 4-aminopyrazolo[2,3-a]pyrimidine and simple compositions thereof.

Group (II), claim(s) 2(part) and 8(part), drawn to compounds wherein the core is a tetraazaacenaphthylene and simple compositions thereof.

Group (III), claim(s) 4-7, drawn to methods of intended use with the compounds of Group (I).

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) Group I -Group III lack unity of invention since under 37 CFR 1.475:

> Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features…those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The technical feature corresponding to Groups (I) is the 4-aminopyrazolo[2,3-a]pyrimidine bicycle while the special technical feature of Group (II) is the tetraazaacenaphthylene tricyclic core. The special technical feature of Group (III) is the method of intended use with the corresponding compounds from Groups (I). Therefore Groups (I-III) are

not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature.

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only the product.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder Advisory

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Laura Madden on April 14, 2008 a provisional election was made without traverse to prosecute the invention of Group (I), claims 1, 2(part), 3 and 8(part). Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-7are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Substituted 4-Aminopyrazolo[2,3-a]pyrimidines as CRF Receptor Antagonists.

Information Disclosure Statement

The information disclosure statement filed 8/8/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

This application contains claim 2(part), drawn to an invention nonelected with traverse in the paper of 4/9/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claim 2 is objected to because of the following informalities: claim 2 is a repeat of claim 1, except for the intended use. The intended weight is not given patentable weight. Appropriate correction is required.

Claim 8 is objected to because of the following informalities: claim 8 is a repeat of claim 3. Both claims are drawn to simple compositions with the compounds of claim 1 or 2, which are the same in scope. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

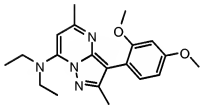
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

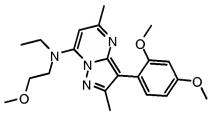
Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et. al. (US 6664261 B2).

The instant application claims the following compounds:

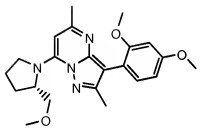
1) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-(diethylamino)pyrazolo[2,3-a]pyrimidine,



2) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-(N-ethyl-N-methoxyethylamino)pyrazolo [2,3-a]pyrimidine,

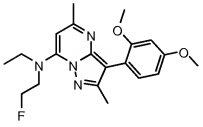


3) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-{2-(S)-methoxymethylpyrrolidinyl}-pyrazolo [2,3 -a]pyrimidine, and

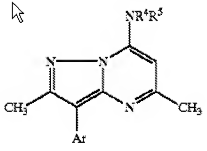


4) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-(N-ethyl-N-{ 2- fluoroethyl}amino)pyrazolo [2,3-

a]pyrimidine.



Chen et. al. teaches compounds of the genus formula (I), column 2, lines 45-55. Also, see subgenus in Table 4, column 17.



One species taught by the reference is wherein Ar= 2,4-dimethoxy, R^4= n-propyl and R^5= methoxyethyl. See compound 51 in Table 4, column 17.

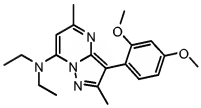
The only difference between the above specie and the specie labeled as **2)** is a propyl versus Applicant's ethyl at R^4. The MPEP 2144.09 states "Compounds which are … homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). Furthermore to the genus in column 2, lines 45-55, teaches that R4 can be ethyl, see line 61. Moreover, the genus also teaches that R4 and R5 can be ethyl, taken together form 2-methoxymethylpyrrolidinyl and 2-fluoroethyl. See column 2, lines 61-67 and

column 3, lines 1-8. Also, there are guideposts which teach ethyl, see Table 4, compound 81, and 2-methoxymethylpyrrolidinyl, see Table 4, column 21, example 128. Thus, said claims are rendered obvious by Chen et. al.

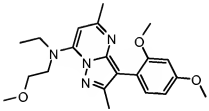
Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et. al. (US 6432989 B1).

The instant application claims the following compounds:

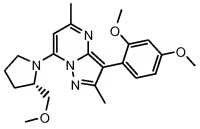
1) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-(diethylamino)pyrazolo[2,3-a]pyrimidine,



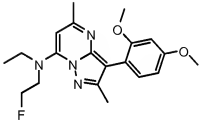
2) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-(N-ethyl-N-methoxyethylamino)pyrazolo [2,3-a]pyrimidine,



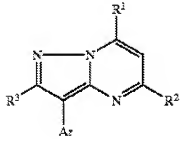
3) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-{2-(S)-methoxymethylpyrrolidinyl}-pyrazolo [2,3 -a]pyrimidine, and



4) 2,5-dimethyl-3-(2,4-dimethoxyphenyl)-7-(N-ethyl-N-{ 2- fluoroethyl}amino)pyrazolo [2,3-a]pyrimidine.



Chen et. al. teaches compounds of the genus formula (I), column 25, lines 50-58. One species taught by the reference is wherein Ar= 2-methyl-4-dimethoxyphenyl, R^1= diethylamino, R^2 and R^3= methyl. See compound 51 in Table 4, column 17.



The only difference between the above specie and the specie labeled as 1) is a methyl versus Applicant's methoxy on the Ar group. The genus in column 2, lines 45-55, teaches that R4 can be ethyl, see line 61. Moreover, the genus also teaches that R4 and R5 can be ethyl,

taken together form 2-methoxymethylpyrrolidinyl and 2-fluoroethyl. See column 26, line 19 teaches the methyl and methoxy are alternatively useable. There are guidepost which point to a dimethoxyphenyl at Ar. See column 33, line 17. Thus, said claims are rendered obvious by Chen et. al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624